

REMARKS

Claims 1-4 and 6 are pending. Claims 5 and 8-23 have been cancelled. Claims 7 and 24-38 have been withdrawn.

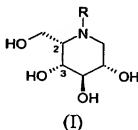
Statement of the Interview

Applicants thank the Examiner for the opportunity to discuss the case on January 28, 2011. During the Interview, the undersigned attorney discussed the rejected claims with the Examiner, requesting withdrawal of the obviousness-type double patenting rejection. No agreement was reached.

Double Patenting

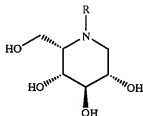
Claims 1-4 and 6 have been provisionally rejected for being unpatentable over claims 1-10 and 13 of co-pending application number 10/522,208 (the '208 application) on the ground of non-statutory obviousness-type double patenting.

Independent claim 1 of the current application is directed to a compound of Formula (I), wherein R is phenylmethyl-, wherein phenyl is substituted by OR¹; and R¹ is C₄₋₅ alkyl:



in free or a pharmaceutically acceptable salt form.

Claim 1 of the '208 application is directed to a compound of formula (I) in free or pharmaceutically acceptable salt form:



(I)

“wherein

R is $-C_{1-3}alkylAr^1$ where Ar^1 is phenyl;

wherein phenyl is substituted by one or more substituents selected from CN , $CON(R^1)_2$, SO_nR^2 , $SO_2N(R^1)_2$, $N(R^5)_2$, $N(R^1)COR_2$, $N(R^1)SO_nR^2$, $C_{0-6}alkylAr^2$, $C_{2-6}alkenylAr^2$ and $C_{3-6}alkynylAr^2$. .

and the Ar^1 phenyl is optionally substituted by one or more additional substituents selected from F, Cl, Br, CF_3 , OCF_3 , OR^3 and $C_{1-6}alkyl$; . . .

R^3 is H, or $C_{1-6}alkyl$;”.

The Examiner argued that claims 1-4 and 6 of the current application are unpatentable in view of claims 1-10 and 13 of the ‘208 application because “US’208’s genus claims clearly encompasses the species as claimed by Applicant”. *Office Action* 2/3/2011, page 5. The Examiner therefore rejected the claims on the ground of obviousness-double patenting.

Applicants respectfully disagree. Applicants first take this opportunity to correct the statement made in the response filed February 9, 2011 that the benzyl is not substituted with $C_{4-6}alkoxy$ group because it is true that the R substituent of the compound of Formula I of the ‘208 Application may be $-C_{1-3}alkylAr^1$ wherein the Ar^1 phenyl may optionally be substituted with one or more additional substituents selected from, among others, OR^3 wherein R^3 may be H or $C_{1-6}alkyl$. Applicants nevertheless disagree with the Examiner that the claims of the current application and the claims of the ‘208 application have patentably indistinct genus-species relationship for the following reason. Generic claim 1 of the ‘208 application requires that the Ar^1 phenyl of the $-C_{1-3}alkylAr^1$ be substituted with one or more substituents selected from “ CN , $CON(R^1)_2$, SO_nR^2 , $SO_2N(R^1)_2$, $N(R^5)_2$, $N(R^1)COR^2$, $N(R^1)SO_nR^2$, $C_{0-6}alkylAr^2$, $C_{2-6}alkenylAr^2$ and $C_{3-6}alkynylAr^2$...” and provides that Ar^1 phenyl may optionally be substituted with one or more additional substituents selected from, among others, OR^3 wherein R^3 may be H or $C_{1-6}alkyl$. (Emphasis added). As such, the Ar^1 phenyl is only additionally substituted with, among others, OR^3 if Ar^1 is first substituted with one or more substituents selected from “ CN , $CON(R^1)_2$, SO_nR^2 , $SO_2N(R^1)_2$, $N(R^5)_2$, $N(R^1)COR^2$, $N(R^1)SO_nR^2$, $C_{0-6}alkylAr^2$, $C_{2-6}alkenylAr^2$ and $C_{3-6}alkynylAr^2$...”. In other words, OR^3 substituent is a selection when Ar^1 phenyl is di-, tri-substituted, etc. In contrast, the compound of the currently claimed invention contains a

benzyl group specifically mono-substituted with a C₄alkoxy group (i.e., wherein R¹ is C₄alkyl). Consequently, the compound of the current invention is patentably distinct from those claimed in the '208 application and the Examiner has erroneously interpreted the claims in the '208 application to be a genus encompassing the species of the currently claimed invention.

Even if the claims of the current invention have a genus-species relationship with the claims of the '208 application (i.e., the '208 application dominates the current application), which Applicants remain to argue that is not the case, MPEP 804 explicitly warned that: "[d]omination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection." MPEP 804, citing *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964). If not based on anticipation, the obviousness-type double patenting determination should parallel the guidelines for a 35 U.S.C. 103(a) rejection. MPEP 804. In this regard, the Federal Circuit has held that a disclosure of a generic formula does not by itself render obvious a species of that genus, *See In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.") (Citation omitted). Extending the analysis of *Baird*, a claim covering a genus does not by itself render a claim covering the species patentably indistinct and unpatentable.

In analyzing obviousness under § 103(a), the Federal Circuit clearly stated in *Eisai Co. LTD v. Dr. Reddy's Laboratories, LTD.*, 533 F.3d 1353 (Fed. Cir. 2008) that "a prima facie case of obviousness for a chemical compound [] begins with the reasoned identification of a lead compound." *Id.* at 1359. Also in *Takeda Chemical Industries, LTD v. Alpharm PTY., LTD*, 492 F.3d 1350 (Fed. Cir. 2007), the Court stated that "[i]n addition to structural similarity between the compounds, a prima facie case of obviousness also requires a showing of 'adequate support in the prior art' for the change in structure." *Id.* at 1356. In the recent case *Daiichi Sankyo Co., LTD. v. Matrix Lab. LTD.*, 2010 WL 3504759 (Fed. Cir. 2010), the Court again reiterated that "proving a reason to select a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds. [] Potent and promising activity in the prior art trumps mere structural relationships." *Id.* at *5 (emphasis added). In particular, the Court explained: "it is the

possession of promising useful properties in a lead compound that motivates a chemist to make structurally similar compounds”, warning that “attribution of a compound as a lead compound after the fact must avoid hindsight bias”. *Id.*

Here, Applicants respectfully submit that the Examiner erred in interpreting the claims of the ‘208 application to be patentably indistinct from the claims of the current invention. The Examiner further erred in ignoring the explicit warning in MPEP Section 804 and rejecting the claims of the current invention based solely on the erroneous ground that claims of the co-pending ‘208 application dominates the claims of the current application. In doing the obviousness-type double patenting analysis, the Examiner also failed to provide any rationale whatsoever as to why the claims of the current invention are obvious and patentably indistinct from those of the ‘208 application. Specifically, the Examiner failed to follow the lead-compound test by failing to identify a reason for plucking the –OR³ substituent from the group of substituents listed in claim 1 of the ‘208 application and ignoring that the Ar¹ phenyl must also be substituted with other specific substituents that are not claimed in compounds of the current invention. Nothing in the claims (or the specification) of the ‘208 application points a skilled artisan to select the currently claimed compound (i.e., the compound wherein R is benzyl mono-substituted with OR¹ wherein R¹ is C₄₋₅alkyl) as the compound of choice to pursue out of a large number of possibilities. The Examiner can only identify the currently claimed compound as the compound of choice based on improper hindsight knowledge of the current invention.

For reasons stated above, reconsideration and withdrawal of the rejections of claims 1-4 and 6 are earnestly requested.

This response is filed within three months from the mailing date of the non-final office action, which response is due May 3, 2011. It is believed no fees are due. Should this be incorrect, please charge any additional fees required during the pendency of this application (including any extension of time fees, except for payment of issue fees) or credit overpayment to Deposit Account No. 50-4255.

Respectfully submitted,

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